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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/621,401	07/18/2003	Craig A. Rosen	PZ020P2C1	6102
22195	7590	06/29/2004	EXAMINER	
HUMAN GENOME SCIENCES INC INTELLECTUAL PROPERTY DEPT. 14200 SHADY GROVE ROAD ROCKVILLE, MD 20850			ZEMAN, MARY K	
			ART UNIT	PAPER NUMBER
			1631	

DATE MAILED: 06/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/621,401

Applicant(s)

ROSEN ET AL.

Examiner

Mary K Zeman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Applicant's election of Group II, claims 24-57, and SEQ ID NO: 145 in the reply filed on 5/5/01 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 24-57 are examined herein.

Priority

Priority to a series of US provisional, non-provisional and PCT applications is acknowledged. The first full disclosure of the elected sequence (SEQ ID NO: 145) appears to be in PCT US98/23435 as SEQ ID NO: 141. The instant claims are accorded the effective filing date of 11/4/98.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

35 U.S.C. 101/112 Utility Rejections

The pending claims have been reviewed in light of the Utility Examination Guidelines and Guidelines for Examination of Patent Applications under 35 U.S.C. 112,

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first paragraph, "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1092-1111, Friday, January 5, 2001.

35 U.S.C. § 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Claims 24-57 are rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility due to its not being supported by a specific, substantial, and credible utility or a well established utility.

The claimed subject matter is not supported by a specific, substantial, and credible utility because the disclosed uses are generally applicable to broad classes of this subject matter. In addition, further characterization of the claimed subject matter would be required to identify or reasonably confirm a "real world" use. The examiner does not find an adequate nexus between the evidence of record and the asserted properties of the claimed subject matter.

The specification identifies SEQ ID NO: 145, the elected polypeptide sequence, as being related to "gene 7" at pages 28-30. SEQ ID NO: 145 is also referenced in the table at page 276. At pages 28-30, the specification asserts that the polypeptide sequence encoded by "gene 7" is expressed primarily in the liver and testes.

At pages 28-30 the specification lists a variety of potential activities and tissue "specificities" that may be related to the elected sequence. Activities and specificities for the DNA and/or encoded protein listed in this section include: hepatic, endocrine and reproductive disorders, as well as immune system and hematopoietic system disorders. At no point is the specifically elected sequence tested for any of the listed associations, activities or expression patterns. At no point is a diagnostic test for any disease developed such that the elected sequence is shown to be linked diagnostically to a particular disease. Each of the above activities is very different, and they are substantially non-overlapping. One of skill in the art would not readily be able to determine a use for the claimed sequence upon reading the specification.

At pages 29-30, the specification sets forth a laundry list of potential uses for any protein involved in cell growth and differentiation, including “detection, treatment, and./or prevention of hepatoblastoma, jaundice, hepatitis or liver metabolic diseases and conditions that are attributable to the differentiation of hepatocyte progenitor cells” without specifically linking the claimed protein to any particular type of disorder, activation pathway or other activity. The list of potential uses include the disparate categories of testicular function, other reproductive disorders, inflammatory disorders, cancer, as well as the categories of “hypoproliferative disorders” and “Infectious diseases”. Each of these categories of disease have widely varying etiology, causes, and treatments, and the specification provides no particular evidence linking the claimed protein to any particular disease, or even class of diseases.

The laundry list of potential activities pointed to by Applicant all are general in nature, many are conflicting, many have widely varying causes or effects such that upon reading the specification, one of skill in the art would not be readily able to determine a specific substantial and credible utility for the claimed polypeptides.

The specification was further probed for information as to a specific substantial and credible utility for the claimed peptide. At page 276, in the table, SEQ ID NO: 145 is identified as being encoded by SEQ ID NO: 17. The table asserts that the polypeptide has a signal sequence beginning with amino acid 1, and ending with amino acid 15, and asserts that the secreted portion would be from amino acids 16-194. This information was all generated by computer analysis and has not been validated by producing the polypeptide in vitro and observing cleavage and secretion of the actual sequence. No such experiments are set forth in the specification as filed. No particular activities or functions are specifically linked to any form of the polypeptides being claimed.

Absent factual evidence, one skilled in the art would have reason to doubt that sequence similarity alone would reasonably support the assertion that the biological activity of the claimed subject matter would be the same as that of the similar sequence. Note that it would have been well known in the art that sequence similarity does not reliably correlate to structural similarity and that structural similarity does not reliably result in similar or identical biological activities. For example, it would have been well

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known that even a single nucleotide or amino acid change or mutation can destroy the function of the biomolecule in many instances, albeit not in all cases. In the absence of factual evidence characterizing the structural and functional components of the biomolecule, the effects of these changes are largely unpredictable as to which ones will have a significant effect and which ones will be silent mutations having no effect. Several publications document the unpredictability of the relationship between sequence, structure, and function, although it is acknowledged that certain specific sequences have been found to be conserved in biomolecules having related function following a significant amount of further research. See Iyer et al. *Genome Biology* 2001 2 (12) pages 1-11; and Baker et al. *Science*, October, 2001, Vol. 294 pages 93-95. (Each of record in parent application 09/974879) However, this level of factual evidence is absent here.

General uses of polypeptides set forth in the specification, as filed, treatment or prevention of unidentified diseases, identification of binding partners, use in production of antibodies to the polypeptides, etc. These general uses are not specific and substantial, as they do not require any one particular sequence. Further, they provide no specific information about any one sequence. For example, for the asserted utility of prevention, diagnosis or treatment of a disease, one would need to know what disease is linked to the polypeptide, and in what way- i.e. does the disease result from too much or too little of the claimed polypeptide. Therefore one of ordinary skill in the art would have to perform additional tests to determine which specific disease could be linked, how it could be linked, and whether or not the peptide itself can be used to treat, prevent or diagnose that disease.

The need for such further research and experimentation clearly indicates that the asserted utilities for the polypeptides are not disclosed and therefore are not specific, substantial and credible utilities. Further no well established utility is supported for any one polypeptide. A starting material that can only be used to produce a final product does not have substantial asserted utility in those instances where the final product is not supported by a specific and substantial utility. Identifying and studying the properties of the claimed subject matter itself or the mechanisms in which the claimed subject matter is involved does not define a "real world" context or use. Similarly, the other listed and

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asserted utilities as summarized above or in the instant specification are neither substantial nor specific due to being generic in nature and applicable to a myriad of such compounds. Neither the specification as filed nor any art of record discloses or suggests any property or activity for the claimed polypeptides such that another non-asserted utility would be well-established for the compounds.

Applicant should explicitly identify a specific, substantial, and credible utility for the claimed invention and establish a probative relation between any evidence of record and the originally disclosed properties of the claimed invention.

Claims 24-57 are also rejected under 35 U.S.C. § 112, first paragraph. Specifically, since the claimed invention is not supported by a specific, substantial, and credible utility or a well-established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 34-47 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The above rejected claims recite polypeptides having various levels of similarity or homology to SEQ ID NO: 145 or the related deposit. The specification, as filed, fails to provide written description of polypeptides meeting the limitations of the claims. The specification provides SEQ ID NO: 145, identifies the signal sequence, and potentially secreted portion.

Written description of an invention requires "a precise definition, such as by structure, formula, chemical name, or physical properties." *Eli Lilly*, 119 F.3d at 1566, 43 USPQ2d at 1404. The specification does not set forth any of these definitions for

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other polypeptides which fall within the scope of the claims. An applicant may also show written description of an invention by combining a partial structure, physical properties, or chemical characteristics with a known or disclosed specific function. However, no specific function or activity had been ascribed to any one elected sequence in the specification, as filed.

The written description requirement for any claim drawn to a genus can be met through sufficient description of a representative number of species within the genus. The broadest claim for each the polypeptide is a separate genus. The specification, as filed, only discloses the single species of the genus, which is not sufficient to support the assertion that Applicant was in possession of the entire genus being claimed.

Therefore, claims drawn to purified polypeptides comprising the sequence set forth in SEQ ID NO: 145 (or shorter forms thereof), but not the full breadth of the claims, would meet the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

Claims 29-33, 41-47 and 53-57 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The deposit of biological organisms is considered by the Examiner to be necessary for enablement of the current invention see 37 CFR 1.808(a). Specifically, it is noted that the above rejected claims either recite deposited material in the body of the claim or depend from claims reciting the deposited material. The Examiner acknowledges the deposit of organisms under ATCC accession number 209368 in partial compliance with this requirement. However, the deposits are not in full compliance with 37 CFR 1.803-1.809.

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If a deposit is made under terms of the Budapest Treaty, then an affidavit or declaration by Applicants or person(s) associated with the patent owner (assignee) who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty *and* that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 CFR 1.808.

If a deposit is not made under the terms of the Budapest Treaty, than an affidavit or declaration by Applicants or person(s) associated with the patent owner (assignee) who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, should be submitted stating that the deposit has been made at an acceptable depository *and that* the following criteria have been met:

- 1) during the pendency of the application, access to the deposit will be afforded to one determined by the Commissioner to be entitled thereto;
- 2) all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent;
- 3) the deposit will be maintained for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposited material;
- 4) a viability statement in accordance with the provisions of 37 CFR 1.807; and
- 5) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

Conclusion


No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (571) 272 0723

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P Woodward can be reached on (571) 272 0722. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. **Should you have questions on the contents of the electronic file, or on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).**


MARY K. ZEMAN
PRIMARY EXAMINER
10/631
6/25/04